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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,295	10/28/2003	Joseph A. Gonzales	A-2966-AU	4188

21378 7590 03/28/2006

APPLIED MEDICAL RESOUCES CORPORATION

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EXAMINER

AHMED, AAMER S

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,295

Applicant(s)

GONZALES ET AL.

Examiner

Aamer S. Ahmed

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 11-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date 03/01/2006. 12/19/05

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: IDS 12/19/2005.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gravener et al U.S. 5,360,417. Gravener et al ('417) discloses a surgical valve (12) having an axis extending between a proximal (16) and a distal end (10), comprising a housing (12) including a proximal (26) housing portion and a distal housing portion (18) cooperating with the proximal housing portion (26) to define a gel cavity (42), a seal material disposed in the gel cavity, the seal material including a gel having non-compressible characteristics; a proximal guide tube (22) extending axially proximally from the proximal housing portion; the proximal guide tube facilitating insertion of a surgical instrument into the seal material, a distal guide tube (18) extending axially distally from the distal housing portion, the distal guide tube facilitating retrograde insertion of the surgical instrument (44) into the surgical seal (see figure 7); and wherein the proximal guide tube (22) includes exterior portions (22) extending proximally of the proximal housing portion (26); and interior portions (34) extending distally of the proximal housing portion (26); and wherein the seal material (42) defines an axial channel through the gel; and the proximal guide tube (22) contacts the seal material around the axial channel at the proximal end of the valve (see figure 7); and wherein the seal material and the first housing portion form a subassembly free of a circumferential seal between the seal material and the first

housing portion; and subassembly to form a circumferential seal between the gel and the first housing portion the proximal guide tube applies a force to the seal material in the subassembly to form a circumferential seal between the gel and the first housing portion (see figure 7).

Furthermore, Gravener ('417) discloses, a node (32) and an axial channel cavity (see figure 7), the seal material being configured with the channel in an open state, (see figure 7) a subassembly including the seal material disposed in the gel a second housing portion disposed in juxtaposition to the first housing portion and applying a force to the seal material in the subassembly, the force being of a magnitude sufficient to place the channel of the seal material in a closed state (see figures 8 and 9); and wherein the guide tube (22) contacts the node (32) of the seal material to apply the force to the seal material.

Moreover, Gravener et al ('417) teaches, a gel disposed (42) within the gel cavity and having properties including flowability and incompressibility, the gel having characteristics for creating a pressure on the instrument to form a seal with the instrument, and means for moving the second housing portion relative to the first housing portion to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve (col. 4 line 64).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gravener et al ('417) in view of Mollenauer et al U.S. Patent Number 5,514,109. Gravener et al ('417) discloses the valve as described above in reference to claim 1. Gravener fails to explicitly describe a luer lock coupled to the distal housing portion. Mollenauer ('109) describes a similar surgical valve with a luer lock (242), see figure 11. It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the surgical valve of Gravener et al ('417) by incorporating a luer lock of the type taught by Mollenauer et al ('109) in order to attach the tubing to the housing.

Response to Arguments

Applicant's arguments filed on December 17th, 2005 have been fully considered but they are not persuasive. Applicant argues that when inserted, the surgical instrument is in actual contact with the seal, however, this limitation is not recited in the claims, furthermore, applicant argues that Gravener fails to disclose a distal guide tube, however this element is disclosed by Gravener as indicated above. In addition applicant argues that Gravener does not disclose the valve in an open state, however, as indicated above Gravener shows the valve in an open (figure 7) and closed (figure 8 and 9) state. Applicant also argues regarding claim 6 that the term "and" should not be present, however the claims as written include the term.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the

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teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the surgical valve of Gravener et al ('417) by incorporating a luer lock of the type taught by Mollenauer et al ('109) in order to attach the tubing to the housing.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A. Ahmed

